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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,497	04/11/2001	Robert S. Behl	16807001530	1252

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,497

Applicant(s)

BEHL ET AL.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-55, 57-58, and 63-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-34, 39, 40, 45-54, 57, 58, 63 and 64 is/are rejected.
- 7) ☒ Claim(s) 35-38, 41-44 and 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 57, 58, 63 and 64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The Applicant inappropriately claims printed subject matter (written instructions).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 39-40, and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Farley et al. ('719).

Independent claim

Farley et al. (Farley) discloses a system for treating a target region beneath a tissue surface, said system comprising:

a probe (10) having a distal end (15) adapted to be positioned beneath the tissue surface to a site in the tissue;

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a plurality of electrodes (34) deployable (fig. 2 – deployed; fig. 5- non-deployed) from the distal end of the probe to span a region of tissue proximate the target region; and a

cover (80, figs.19-20) removably attachable to the probe and adapted to span a region of tissue proximate the target region.

Dependent claims

Re: claim 33, Farley depicts in fig. 20 a cover (80) with a flat face.

Re: claims 39 and 40, Farley discloses a connector (82; fig. 20) which is selectively attachable at different axial positions along the probe (col. 22:49-54).

Re: claims 45 and 46, Farley discloses a probe comprising a cannula (fig. 2; 12) having a proximal end, a distal end, and wherein the plurality of three electrodes (34) are resilient (indicated by comparing the electrode leads 30 in fig. 2 to those in fig. 5) and disposed in the cannula lumen to reciprocate between a proximally retracted position wherein all electrodes are radially constrained within the lumen (fig. 5) and a distally extended position wherein all electrodes deploy radially and everted outwardly (fig. 2).

Re: claim 47, Farley discloses rods (30).

Re: claim 48, Farley discloses a tissue penetrating member or electrode (35) that could permit advancement of the cannula through tissue.

Re: claim 49, Farley discloses a stylet (53, fig. 8a). Note: intended use language as that found in claim 49 is given little weight during examination. The Examiner is

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obligated to show structures and not intended use of the structures in the prior art for valid rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 50-54, 57-58, and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farley et al. ('719).

Farley neglects to expressly disclose cover, cannula, or electrode dimensions.

However, the Examiner contends that one of ordinary skill in the art would have ascertained the optimal values (assuming that the parameters in the Applicant's claims are optimal) for these parameters via routine experimentation. The motivation to acquire these parameters would be to develop a superior protocol.

Re: claims 57-58, 63 and 64, the Examiner has applied the above rejections toward all limitations in the claims (57-58, 63,64) excluding the written steps of the instructions, which as indicated above are non-statutory subject matter. Further, it would have been obvious at the time of the invention to include written instructions with the Farley device in order to instruct the device operators of safe and effective usage.

Allowable Subject Matter

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Claims 35-38, 41-44, and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art neglects to disclose or make obvious a cover in the context disclosed by the Applicant with surface electrodes (see application fig. 4; elements 24 and 52).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. LaFontaine ('594), Motamedi et al. ('019), Berube et al. ('427), Cragg ('789), Kontos ('266), Gambale et al. ('778), Turi ('341), Swanson et al. ('473), Moaddeb et al. ('580), LeVeen et al. ('576) ('276).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
February 7, 2003

PV


MICHAEL PEFFLEY
PRIMARY EXAMINER